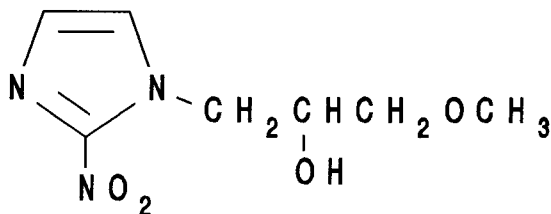


MISONIDAZOLE

NSC - 261037



Chemical Name: α -(Methoxymethyl)-2-nitro-1H-imidazole-1-ethanol

Other Names: Ro-7-0582, 1-(2-nitroimidazolyl)-3-methoxy-2-propanol

CAS Registry Number: 13551-87-6

Molecular Formula: C₇H₁₁N₃O₄

M.W.: 201.2

How Supplied: For injection, 500 mg, vial: supplied as a light yellow lyophilized powder with 300 mg of mannitol, USP, in 30 mL amber vials.

Solution Preparation: 500 mg/vial: When constituted with 19.6 mL of 0.9% Sodium Chloride Injection, USP, or Sterile Water for Injection, USP, each milliliter contains 25 mg of misonidazole and 15 mg of mannitol, USP, pH 5.0 to 7.0.

CAUTION: Some vials contain undissolved misonidazole after constitution. Complete reconstitution can be achieved by warming the mixture at 40 °C or constituting with 25 mL of diluent initially for a misonidazole concentration of 20 mg/mL.

Storage: Store the vials at room temperature (22-25 °C).

Stability: Shelf-life surveillance studies are continuing. The intact vials are stable for at least 3 years at room temperature (22-25 °C). The intact vials are stable for at least one year when stored at elevated temperature (50 °C).

Constitution of the vials as directed results in a solution which is chemically stable for at least 14 days at room temperature, exhibiting less than 2% decomposition.

Further dilution of the freshly constituted solution to a concentration of 1 gm/L in 5% Dextrose Injection, USP, resulted in less than 1% decomposition in 14 days at room temperature.

The stability of solutions of misonidazole is unaffected by exposure to light.

CAUTION: The single-use lyophilized dosage form contains no antibacterial preservatives. Therefore, it is advised that the constituted product be discarded within 8 hours of initial entry.

Route of Administration: Intravenous